

U.S. Patent Application No. 10/523,572
Amendment dated November 21, 2007
Reply to Office Action of August 24, 2007

REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

By way of this amendment, claim 1 has been amended to incorporate some of the limitations of claim 7 into claim 1. Claims 5, 6, 8, and 9 have been amended to make them dependent on claim 1. Claims 3, 4, and 7 have been canceled by way of this amendment. The non-elected claims, namely claims 12-21 have been withdrawn. Full support for the amendments can be found throughout the present application and the claims as originally filed, for instance, in claims 3, 4, and 7 and page 16 of the present application. Further, by way of this amendment, Tables 1 and 2 in the present application have been amended to address an objection by the Examiner. More specifically, the objected to parts at pages 28 and 32 have been deleted and tables have been substituted in their place. The tables and the information in the tables are set forth in the PCT application, namely PCT/JP2003/009795 at pages 18, 19, and 21. A copy of the International application was submitted to the U.S. Patent and Trademark Office at the time of filing this application on January 28, 2005. It is noted that under M.P.E.P. §201.17, the specification can be amended to include these tables from the International application since the present application is a National Stage application of PCT/JP03/009795, and the present application is an English translation of this PCT application. Clearly, a translational error occurred by not including this information in the tables and this information was originally filed in the International application. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

Restriction Requirement and Election of Species Requirement

At page 2 of the Office Action, the Examiner acknowledges the election of claims 1-11 and

U.S. Patent Application No. 10/523,572
Amendment dated November 21, 2007
Reply to Office Action of August 24, 2007

that the elected species is polyamino acid. The Examiner indicates that claim 18 is a separate, non-elected invention.

By way of this amendment, the non-elected claims have been indicated as "withdrawn."

Objection to the Specification

At page 2 of the Office Action, the Examiner objects to the specification because the Examiner states that Tables 1 and 2 are missing data. This rejection is respectfully traversed.

As explained above, this information has now been included in the application and is entirely based on the International application, wherein the present application is a National Stage of this International application. Accordingly, this objection should be withdrawn.

Objection to Figures

At page 2 of the Office Action, the Examiner objects to Figures 5-7, 8-1, 8-2, 9-1, 9-2, 10-1, 10-2, 11-1, 11-2, 12-1, and 12-2 for being of poor quality. This rejection is respectfully traversed.

During a telephone conference with the Examiner on November 19, 2007, the applicants' representative sought clarification on the Examiner's objection to the drawings. The applicants' representative pointed out that copies of the filed drawings appeared acceptable. The Examiner stated that nothing appears in Fig. 5 and that the electronic version of the drawings which include photographs appear blurry. The Examiner suggested filing originals of the drawing which include photographs.

With respect to the Examiner's objection to Figure 5, the applicants' representative pointed out that nothing is depicted in Figure 5 because, as indicated in the specification, nothing could be observed when sample 4 was photographed (Specification, page 29). With respect to the

U.S. Patent Application No. 10/523,572
Amendment dated November 21, 2007
Reply to Office Action of August 24, 2007

Examiner's objection to the remaining drawings, the applicants' representative indicated that more electronically reproducible figures will be provided shortly after the filing of the response. The Examiner indicated that this would be acceptable.

Rejection of claims 1-11 under 35 U.S.C. §112 – Indefiniteness

At page 3 of the Office Action, the Examiner states that claims 1-11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner states that the preamble requires the preparation of platelet-rich plasma, but that the claim lacks a step directed to production of platelet-rich plasma. This rejection is respectfully traversed.

The claims, as currently amended, recite a step directed to separating the platelet-rich plasma, as suggested by the Examiner. Accordingly, the applicants respectfully request withdrawal of this rejection.

Rejection of claims 1-7 and 11 under 35 U.S.C. §102(b) -- Kummer et al.

Beginning at page 3 of the Office Action and continuing to page 4, the Examiner asserts that claims 1-7 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kummer et al. ("Separation of Platelet Rich Plasma and Red Cells with Modified Gelatin," Vox Sang. 24: 76-88 (1973)). The Examiner states that Kummer et al. discloses the addition of Physiogel M to blood, sedimenting the red blood cells, separating the red blood cells and the platelet-rich plasma. The Examiner states that Physiogel M is a succinylated gelatin product. This rejection is respectfully traversed.

The claims, as currently amended, recite the step of adding water soluble polyamino acids that are homopolymers. Gelatin is not a water-soluble polyamino acid that is a homopolymer. Thus,

U.S. Patent Application No. 10/523,572
Amendment dated November 21, 2007
Reply to Office Action of August 24, 2007

even if Physiogel M is a succinylated gelatin product, as suggested by the Examiner, it does not fall within the definition of polyamino acids, as recited in the present claims. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of claims 1-11 under 35 U.S.C. §103(a) -- Kass et al., in combination with Maeda et al. or Yoshimura et al. or Danon

Beginning at page 4 of the Office Action and continuing to page 5, the Examiner states that claims 1-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kass et al. (U.S. Patent No. 5,397,479) in combination with Maeda et al. ("Inhibition and acceleration of erythrocyte aggregation induced by small macromolecules," BIOCHIMICA ET BIOPHYSICA ACTA, 843, 128-136 (1985)) or Yoshimura et al. (U.S. Patent No. 6,673,629) or Danon ("Agglutination of Red Blood Cells by Polyelectrolytes and Antibodies," BIBL. ANAT., No. 11, pp. 289-295 (Karger, Basel 1973)). The Examiner states that Kass et al. discloses a method of separating red cells from blood comprising adding aggregators of red cells such as polysaccharides or proteins to the blood, and that the protein aggregators are described as being fibrinogens and gamma globulin. The Examiner states that Maeda et al. discloses that polyglutamic acid is an aggregator of red blood cells and that polyglutamic acid having a molecular weight of 8000 inhibited aggregation while polyglutamic acid having a molecular weight of 20,000 accelerated the rate of sedimentation. The Examiner states that Yoshimura et al. discloses that polycationic compounds such as polyhistidine are aggregators of red blood cells. According to the Examiner, Danon discloses that polylysine is an agglutinator of red blood cells. The Examiner asserts that substitution of polyglutamic acid or polyhistidine or polylysine or any polycationic peptide for the aggregator in the method disclosed in Kass et al. would have been obvious because Maeda et al. and Danon or Yoshimura et al. discloses that these compounds are aggregators of red blood

U.S. Patent Application No. 10/523,572
Amendment dated November 21, 2007
Reply to Office Action of August 24, 2007

cells. This rejection is respectfully traversed.

Kass et al. relates to a method of separating red blood cells from blood in order to analyze other components of blood, such as, white blood cells and platelets. Kass et al. indicates that the white blood cells are contained in the remaining plasma. Kass et al. also relates to leukocyte-rich plasma (column 2, lines 1-4), but does not disclose obtaining platelet-rich plasma, as recited in the present claims. Kass et al. also does not disclose obtaining platelet-rich plasma by accelerating the sedimentation of the red blood cells in the blood, as recited in the present claims. It should be noted that accelerating the sedimentation of the red blood cells in the blood in obtaining platelet-rich plasma is particularly significant because, as disclosed in the present application, by accelerating the sedimentation of the red blood cells in the blood, it is possible to obtain platelet-rich plasma comprising at least 15% or more of the total blood volume in as little as 20 to 30 minutes (Specification, pages 13 and 23).

The secondary references cited by the Examiner fail to supplement the above-noted deficiencies in Kass et al. None of the secondary references teach or suggest obtaining platelet-rich plasma. Moreover, even if the polysaccharides and proteins used in Kass et al. as aggregating agents, are replaced with polyglutamic acid, polyhistidine, or polylysine, as suggested by the Examiner, platelet-rich plasma cannot be obtained unless the red blood cells are sedimented in an accelerative manner, as discussed in the present specification (page 23).

The applicants also point out that since platelets are very delicate components of the blood, a slight physicochemical environmental change, such as a change in pH, the shearing force when passing a thin hypodermic needle, or friction stress, may cause the platelets to break or be unusually activated. Thus, platelets cannot easily be obtained intact.

Thus, the present invention is directed to methods for obtaining the platelet-rich plasma

U.S. Patent Application No. 10/523,572
Amendment dated November 21, 2007
Reply to Office Action of August 24, 2007

without affecting the function of platelets. The cited references, however, discuss methods of separating red blood cells. As such, the cited references do not alone, or in combination, render the present invention obvious.

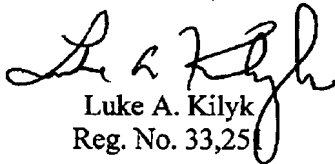
Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



Luke A. Kilyk
Reg. No. 33,251

Atty. Docket No. 3190-073
KILYK & BOWERSOX, P.L.L.C.
400 Holiday Court, Suite 102
Warrenton, VA 20186
Tel.: (540) 428-1701
Fax: (540) 428-1720